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10
                               UNITED STATES DISTRICT COURT
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                             NORTHERN DISTRICT OF CALIFORNIA
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                                       SAN JOSE DIVISION
14
    UNITED STATES OF AMERICA,
                                                CASE NO. 18-CR-00258 EJD
15
          Plaintiff.
                                                STIPULATION AND [PROPOSED] THIRD
16
                                                SUPPLEMENTAL PROTECTIVE ORDER
                                                REGARDING FDA AND CMS DOCUMENTS
17
    ELIZABETH HOLMES and RAMESH
18
    "SUNNY" BALWANI,
19
          Defendants.
20
          The United States of America, by and through ADAM A. REEVES, Attorney for the United
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    States Acting Under Authority Conferred by 28 U.S.C. § 515, and JEFF SCHENK, JOHN C. BOSTIC,
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    and ROBERT S. LEACH, Assistant United States Attorneys for the Northern District of California, and
23
    the defendants, ELIZABETH HOLMES and RAMESH "SUNNY" BALWANI, and their attorneys,
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    KEVIN DOWNEY and LANCE WADE of Williams & Connolly for HOLMES, and JEFFREY B.
25
    COOPERSMITH and STEPHEN A. CAZARES of Davis Wright Tremaine for BALWANI, hereby
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    stipulate and jointly request that the Court issue a third supplemental Protective Order in this case as
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    described below.
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    [PROPOSED] THIRD SUPPLEMENTAL PROTECTIVE ORDER RE FDA AND CMS
    INFORMATION
    18-CR-00258 EJD
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The parties stipulated to, and the Court entered, a Protective Order in this case on or about July 2, 2018 (Docket #28) ("the Original Protective Order"). A Stipulation and Supplemental Protective Order was entered by the Court on July 17, 2019 (Docket #90) ("the Supplemental Protective Order").

During the course of its investigation, the United States has obtained materials from various government agencies, including the Food and Drug Administration ("FDA") and the Centers for Medicare & Medicaid Services ("CMS"), and may obtain additional materials from the foregoing agencies or from other similar government agencies (collectively "the Agencies"). These materials may contain information that the Agencies consider confidential commercial information, trade secrets, Protected Health Information (PHI, as defined in HIPAA), or protected by certain privileges and doctrines, such as work product, attorney-client privilege, and deliberative process. The materials may also contain information unrelated to the defendants or Theranos, Inc. ("Theranos"). The Original Protective Order and the Supplemental Protective Order previously provided procedures to facilitate the production of Private Documents and Government Agency Documents, as those terms are defined in those orders.

After those Protective Orders were entered by the Court, the Court issued an Order on July 19, 2019, instructing the Agencies to search for and produce all documents responsive to the six categories of documents requested by the parties by October 2, 2019. Given this deadline, the Agencies will have limited time to review the potentially responsive documents before production. As a result, non-responsive, privileged, or otherwise protected information, including deliberative internal communications that are not about Theranos, may be produced to the parties. The Agencies have therefore advised that a further order is needed expressly stating that such productions will not be considered a waiver of any privileges or other applicable protections. Deliberative process privileged information that relates specifically to Theranos is not encompassed within this requested order because the Agencies have waived deliberative process privilege for information relating to Theranos.

Accordingly, in order to further facilitate the production of documents by the Agencies, the parties stipulate and agree as follows:

1. The production to the United States, Holmes, and/or Balwani of non-responsive,

privileged, or otherwise protected information in Government Agency Documents, as defined by the Supplemental Protective Order, including but not limited to deliberative internal communications that are not about Theranos contained in such documents, whether knowing or inadvertent, will not be considered a waiver of any privileges or protections that the Agencies may have with regard to such documents or information.

- 2. Deliberative process privileged information that relates specifically to Theranos is not encompassed within this Order because the Agencies have waived deliberative process privilege for information relating to Theranos.
- 3. This Order does not impose any obligation on the defense to identify to the Agencies or the prosecution any material within the production to the United States, Holmes, and/or Balwani of Government Agency Documents that is potentially non-responsive, privileged, or otherwise protected information, including but not limited to deliberative internal communications that are not about Theranos contained in such documents.
- 4. To the extent the Agencies seek to clawback any produced documents as containing non-responsive, privileged, or otherwise protected information, the Agencies shall provide the defense with notice of such clawback by providing the Bates numbers of such documents.
- 5. The defense does not waive, and instead explicitly preserves, any and all arguments that material within the production to the United States, Holmes, and/or Balwani of Government Agency Documents is responsive, not privileged, or otherwise not protected from discovery.

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1	6. The parties stipulate to this Order without prejudice to their ability to seek to modify the	
2	terms of the Order at a future	e date.
3 4	DATED: September 17, 2019	Respectfully submitted,
5		ADAM A. REEVES Attorney for the United States
6 7		Acting Under Authority Conferred by 28 U.S.C. § 515
8		<u>/s/</u> JEFF SCHENK JOHN C. BOSTIC
9		ROBERT S. LEACH Assistant United States Attorneys
1 2	DATED: September 17, 2019	
3		/s/ KEVIN DOWNEY LANCE WADE Attorneys for Elizabeth Holmes
5		Attorneys for Enzabeth Homies
6	DATED: September 17, 2019	
8		<u>/s/</u> JEFFREY B. COOPERSMITH STEPHEN A. CAZARES
9		Attorneys for Ramesh "Sunny" Balwani
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22	SO ORDERED.	
24	DATED:	HONORABLE EDWARD J. DAVILA
25 26		United States District Court Judge
27		
28	[PROPOSED] THIRD SUPPLEMENTAL PROTECTION	CTIVE ORDER RE FDA AND CMS

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